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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/026,952 | 12/27/2001 | Irina Nazarenko | 0942.4980006/RWE/AGU | 7365 |
| 26111 | 7590 | 06/02/2004 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | TUNG, JOYCE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,952

Applicant(s)

NAZARENKO ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,11 and 76-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,11 and 76-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/5/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 2/12/2004 has been entered. Claims 9, 11 and 76-88 and pending.

1. The rejection of claims 10 and 11 under 112, second paragraph is withdrawn.
2. The rejection of claims 9-11 under 35 U.S.C. 102 (e) as being anticipated by Dale (US 6,440,723, issued 8/27/2002) is withdrawn.

NEW GROUNDS OF REJECTION NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 9, 11 and 76-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dale (US 6,440,723, issued 8/27/2002) in view of Kolocheva et al. (Biochimie, 1996, Vol. 78. pg. 201-203).

Dale discloses an array having associated polymer sequences with modified structure and kits containing such array (See column 1, lines 61-66). The modified structure comprises modifications to the sugar moieties (e.g., 2'-substituted ribonucleotide monomer) (See column 5, lines 63-67 to column 6, line 1). The chemical modification of the oligonucleotide may be at 5' end or 3' end (See column 6, lines 32-45). One or more alkyl can be placed on either end of the oligonucleotide (See column 12, lines 65-67 to column 13, lines 1-2), for example, 2'-O-alkyl (See column 13, lines 11-15). The invention also includes a kit containing the array associated with modified polymer, polymerase and reverse transcriptase (See column 26, lines 9-29).

Dale does not disclose that the modified nucleotide is not complementary to the corresponding nucleotide of the target nucleic acid molecule, thereby rendering the oligonucleotide less extendable.

Kolocheva et al. disclose a comparison study of maximal rates of extension for primers containing different modified bases or mismatches and fully complementary primers catalyzed by the Klenow DNA polymerase. The modification is at 3' terminus. The finding is that removal of one base in any position from the 3'-terminus of the primer is equivalent of shortening of the primer by one nucleotide unit and decreases the affinity to the enzyme by 1.8-fold. The efficiency of elongation of the primer is decreased (See pg. 201).

Thus one of ordinary skill in the art would have been motivated to modify the nucleotide at 3' terminal to make it non-complementary to the corresponding nucleotide of the target nucleic acid molecule, thereby rendering the oligonucleotide less extendable as taught by Kolocheva et al. because of the study of Kolocheva et al. It would have been prima facie obvious

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to construct the composition comprising one or more target nucleic acid molecules, at least one oligonucleotide comprising a modified nucleotide at or near its 3' terminal which is not complementary to the corresponding nucleotide of the target nucleic acid molecule, thereby rendering the oligonucleotide less extendable.

Summary

5. No claims are allowable.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung JT
May 26, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/27/04